

Notice of Allowability

Application No.

09/935,386

Examiner

Thaia N. Ton

Applicant(s)

YU, JOHN C.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/22/04.
2. ☒ The allowed claim(s) is/are 1,3-9 and 17.
3. ☒ The drawings filed on 02 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Reasons for Allowance

Applicants' Response, filed 2/22/05, has been considered. Applicants argue that in the Advisory Action, mailed 12/20/04, the Examiner stated that conditions, such as the amount of radiation administered and the number of cells implanted would have to be considered with regard to enablement. See p. 2 of the Response. Applicants traverse this rejection and point to the specification for support for the amount of radiation administered in the process of making the *in vivo* model of human leukemia, as presently claimed. Applicants further point to the final claimed step, which states allowing the primary human leukemia cells to engraft in the mouse to produce the *in vivo* model of human leukemia, and that there is no prior art of record that supports a finding such that one of ordinary skill in the art could not practice the invention. See p. 3 of the Response.

Applicants' arguments are found to be persuasive. In particular, the Examiner provides the following statement of reasons for allowance: the prior art of record neither teaches or suggests that claimed invention, a process for making an *in vivo* model of human leukemia comprising preconditioning an immunodeficient mouse by administration of a sub-lethal dose of irradiation and injecting the mouse with an effective pre-conditioning amount of mononuclear cells derived from human fetal cord blood, maintaining the mouse for 5-10 days, injecting the mouse with an effective engrafting amount of primary human leukemia cells, and allowing the primary human leukemia cells to engraft in the mouse to produce the *in vivo* model

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of human leukemia. In particular, the art fails to teach or suggest maintaining the mouse for 5-10 days prior to injecting the mouse with primary human leukemia cells. The closest prior art of record (which was cited in prior Office actions) is Yu *et al.* [Proceedings of the Am. Association for Cancer Research Annual Meeting, March 1999, Vol. 40, page 660, Abstract No. 43521.]. Yu teach the generation of an immunodeficient rodent having fetal cord blood cells and engrafted human leukemia cells. However, there is no teaching or suggestion in Yu with regard to maintenance of the rodent for 5-10 days (as required in the instant claims) prior to the introduction of the primary leukemia cells.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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